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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/680,755

10/07/2003

Penny J. Thompson

02-22

5495

7590

06/27/2006

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EXAMINER

CHANDRA, GYAN

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/680,755

**Applicant(s)**

THOMPSON ET AL.

**Examiner**

Gyan Chandra

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23,27 and 37-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23,27 and 37-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/14/2006.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

**Note:** The applicant was contacted on 6/19/2006 to address the 35 USC 112, second paragraph issues (see the attached interview summary).

### ***Election/Restrictions***

Applicant's election of Group III, claims 23, 26, 27 and 30, in the reply filed on 4/14/2006, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

### **Status of Application, Amendments, And/Or Claims**

Claims 1-22, 24 -26 and 28-36 are canceled. The addition of new claims 37-40 has been made of record.

Claims 23, 27 and 37-40 are pending and under examination.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) filed on 4/14/2006 has been considered.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23, 27 and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Levinson (US Patent NO. 5,721,351).

The claims are drawn to a method of detecting or diagnosing inflammatory bowel disease in a biological sample, comprising screening the sample for the polynucleotide sequence of SEQ ID NO: 1 or a fragment thereof, wherein the inflammatory bowel disease is ulcerative colitis or Crohn's disease.

Levinson teaches methods of diagnosing chronic inflammatory disorders such as Crohn's disease (col. 1, lines 10-15). Levinson teaches that many genes are differentially expressed in a number of diseases, and that these genes can be used for diagnosing inflammatory diseases. Levinson discloses a gene 54 comprising the polynucleotide sequence of SEQ ID NO: 11, which is differentially expressed in TH1 cells. Levinson suggests that the polynucleotide can be used for diagnosing immune disorders (col. 78, lines 29-45). The nucleic acid 1463-1481 of SEQ ID NO: 1 of the instant application is 100% identical to the nucleic acid 1239-1257 of SEQ ID NO: 11 of Levinson (see Appendix-A). Also, the nucleic acids 671-676 of the instant application are 100% identical to the nucleic acids 361-367 of Levinson. Therefore, the method of diagnosing Crohn's disease using the polynucleotide sequence of SEQ ID NO: 11 of Levinson anticipates instantly claimed invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1646

Claims 23 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out method steps for the claimed invention.

Because the method steps in claims 23 and 27 are identical except the preamble "detecting" and "diagnosing", the claims are redundant.

Further, the methods are directed to detecting or diagnosing "inflammatory bowel disease in a biological sample, comprising screening the sample for the polynucleotide sequence of SEQ ID NO: 1 or a fragment thereof". Upon careful review of the specification, the Examiner suggests that the methods should be directed to detecting or diagnosing "inflammatory bowel disease in a subject, comprising obtaining a biological sample from the subject, and screening for the polynucleotide of SEQ ID NO:1, wherein an increase in the level of the polynucleotide of SEQ ID NO: 1 compared to control indicates inflammatory bowel disease".

### ***Conclusion***

No claim is allowed.


Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra, Ph.D.  
Art Unit 1646  
22 June 2006  
Fax: 571-273-2922

  
**EILEEN B. O'HARA**  
**PRIMARY EXAMINER**